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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,801	01/26/2005	Naouki Yamamoto	04703/0202222-US0	1323

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EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
05/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,801	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim 21 as amended and new claim 23 (2/29/2008) are pending and under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 as amended and new claim 23 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,516,684 (Saito et al).

Claims are directed to a method for reducing allergy wherein the method comprises one active step of orally administering to a subject in need of allergy reduction an effective dose of an anti-allergic agent *Lactobacillus acidophilus* strain CL92 (FERM BP-4981). Some claims are further drawn to the characterization of the claimed strain including reduction of antigen-specific IgE level without affecting IgC level upon administration.

US 5,516,684 (Saito et al) discloses lactic acid bacteria that belong to the *Lactobacillus acidophilus* strain CL92 (FERM BP-4981) (page 3, lines 10-20) and teaches a method for treating a subject wherein the method comprises one active step of orally administering to the subject the cells of *Lactobacillus acidophilus* strain CL92 (FERM BP-4981) in amounts 10x4 to 10x11 cells per day (abstract and col. 5, lines 20-68). The cited method comprises one identical active step of administering identical bacterial strain and, thus, the effect of this treatment are reasonably expected to be the same effects including reduction of allergy and/or lowering IgE level without affecting IgC level upon administration. Moreover, the disclosed administration

doses (col. 5, lines 55-60) are the same as intended for the claimed method (specification page 9, lines 1-10).

Therefore, the cited patent US 5,516,684 (Saito et al) anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 21 as amended and new claim 23 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 9-2959 and/or WO 01/37865 taken with US 5,516,684 (Saito et al).

Claims are directed to a method for reducing allergy wherein the method comprises one active step of orally administering to a subject in need of allergy reduction an effective dose of an anti-allergic agent *Lactobacillus acidophilus* strain CL92 (FERM BP-4981). Some claims are further drawn to the characterization of the claimed strain including reduction of antigen-specific IgE level without affecting IgC level upon administration.

JP 9-2959 and WO 01/37865 disclose methods for reducing allergy and lowering IgE levels by orally administering lactic acid bacteria that belong to the species of *Lactobacillus acidophilus*. For example: see JP 9-2959 at English abstract or official translation. WO 01/37865 discloses a method for reducing allergy and lowering IgE levels by orally administering lactic acid bacteria that belong to the *Lactobacillus acidophilus* (entire document including abstract, page 2 at lines 5-15 and pages 8-9). WO 01/37865 teaches that the cells of *Lactobacillus*

acidophilus are capable, when administered orally, to suppress antigen-specific IgE level in blood in a mouse rhinitis model wherein antigen-specific IgE level in blood has been elevated by nasally exposing the mouse to continuous antigen stimulation (pages 8-10).

The disclosed lactic bacteria used for administration are generic bacteria belonging to the biological species of *Lactobacillus acidophilus* (WO 01/37865) or some particular strains belonging to the biological species of *Lactobacillus acidophilus* (JP 9-2959). Thus, the methods of the cited JP 9-2959 and WO 01/37865 are lacking particular disclosure about the use of the claimed particular strain such as *Lactobacillus acidophilus* strain CL92.

However, the *Lactobacillus acidophilus* strain CL92 has been known and used for oral administration as a beneficial feed product as taught by US 5,516,684 (Saito et al).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the methods of JP 9-2959 and/or WO 01/37865 by administering cells *Lactobacillus acidophilus* strain CL92 as active ingredients with a reasonable expectation of success for reducing allergy and lowering IgE levels because cells belonging to the biological species *Lactobacillus acidophilus* have been known, used and/or suggested for reducing allergy and lowering IgE levels as adequately demonstrated by JP 9-2959 and/or WO 01/37865. Thus, substitution of *Lactobacillus acidophilus* strain CL92 for the other strains belonging to the biological species *Lactobacillus acidophilus* is considered to be substitution of equivalents. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 2/29/2008 have been fully considered but they are not persuasive.

With regard to the claim rejected under 35 U.S.C. 102(b) as being anticipated by US 5,516,684 (Saito et al) applicants argue that the cited reference does not expressly discloses the claimed invention because it does not recognize that the strain CL92 belonging to the species *Lactobacillus acidophilus* is capable to suppress IgE levels (response page 5). This argument is not found persuasive because the cited method comprises one identical active step of orally administering identical bacterial strain and, thus, the effects of identical treatment are reasonably expected to be identical effects including reduction of allergy and/or lowering IgE level without affecting IgC level upon administration. Moreover, the disclosed administration doses (col. 5, lines 55-60) are the same as intended for the claimed method (specification page 9, lines 1-10). Therefore, the cited patent US 5,516,684 (Saito et al) is considered to anticipate the claimed method.

With regard to the claim rejection under 35 U.S.C. 103(a) Applicants argue that the cited references fail to teach or suggest that the *Lactobacillus acidophilus* strain CL92 have an anti-allergic effect because teaching of JP 9-2959 and WO 01/37865 is drawn to either different strains or to generic representatives of *Lactobacillus acidophilus* and because the art recognizes that the anti-allergic effects depend "on the bacterial strain rather than on the bacterial species" (response page 7, par. 3). The evidentiary reference from attachment A has been evaluated and found that it actually teaches that degree of anti-allergic activity varies from strain to strain but the microbial species as the whole is characterized as having this anti-allergic activity. Thus, the

cited references JP 9-2959 and WO 01/37865 that clearly recognize that the representatives of the species *Lactobacillus acidophilus* have anti-allergic affects such as reduction of IgE level upon administration clearly provide for a reasonable believe that the prior art strain CL92 that belong the species of *Lactobacillus acidophilus* (US 5,516,684) is capable to reduce IgE level upon administration at least to some degree and within the meaning of the claims.

Further, with regard to the cited JP 9-2959 Applicants argue that the teaching of this reference is insufficient because it demonstrates the anti-allergic effects of *Lactobacillus acidophilus* in the form of killed cells in the in vitro assay (response page 8). Yet, the pending claims are silent about form of cells for administration. Moreover, WO 01/37865 teaches administration of live cells (for example: abstract). Applicants also argue that the art (attachment C) recognizes that results obtained in the in vivo animal models as in WO 01/37865 might not be confirmed in the human subjects. Yet, the pending claims are silent about "subject" or patient under treatment.

Applicants' arguments as drawn to anti-allergic effect exhibited with both live and killed cells and as based on results disclosed in the Declaration by Mr. Fujiwara (response page 9) have been considered however they are not persuasive because the results of the declaration are confusing as to the significance of the differences in anti-allergic effects as indicated. The cited WO 01/37865 clearly teaches administration of live cells for in vivo administration (abstract) and the cited JP 9-2959 appears to recognize the equivalency of anti-allergic effects provided by both killed and freeze-dried (live) bacterial preparations (see translation in the Attachment B at page 6, par. 0012, line 8).

Applicant arguments as based on a possibility of a different mechanism of action (response pages 10-11) as result of using the prior art strain CL92 in view of the findings by others and at the date after the instant application and claims (reference of attachment E) have no persuasive grounds. The cited prior art teaches and suggests therapeutic methods for reducing allergy and lowering IgE levels by oral administration of various representatives of *Lactobacillus acidophilus* (JP 9-2959 and WO 01/37865) and the strain CL92 have been known and used for oral administration. Thus, one of skill in the art would have been motivated to use the strain CL92 because it is suitable for oral administration and because CL92 is a representative of the *Lactobacillus acidophilus* species that is capable for reducing allergy and IgE levels. The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

May 16, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657